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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,772	01/16/2004	Walter H. Gunzburg	2316.1007-001	6313

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/758,772	GUNZBURG ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15 and 17, drawn to a DNA construct comprising at least one therapeutic gene under the control of the WAP or MMTV regulatory sequences, a recombinant viral or plasmid vector as said DNA construct, a recombinant retroviral particle produced by culturing a packaging cell line harbouring a retroviral vector construct, a human cell containing said retroviral provirus, and a cell line containing a construct for the treatment of diseases or disorders of human mammary cells, classified in classes 435 and 424, subclasses 320.1 and 93.2, respectively.

II. Claim 16, drawn to a packaging cell line harbouring a retroviral vector construct according to claim 6 and one or more construct coding for the protein required for the genome of said retroviral vector to be packaged, classified in class 424, subclass 93.2.

III. Claims 18, 19 and 40, drawn to encapsulated cells comprising a core containing cells and a porous capsule wall, and a method for treatment of human mammary carcinoma comprising implanting said encapsulated cells into a human, classified in class 435, subclasses 93.2 and 458.

IV. Claims 20 and 21, drawn to the use of a DNA construct according to claim 1 or the recombinant viral particle according to claim 12 for the preparation of a medicament for the treatment of disorders or diseases of human mammary cells, classified in classes 435 and 424, subclasses 320.1 and 93.6, respectively.

V. Claims 23, 24, 37 and 38, drawn to a pharmaceutical composition comprising the DNA construct according to claim 1 or the recombinant retroviral particle according to claim 12, and a method for the treatment of human mammary carcinoma by using said DNA construct or said recombinant retroviral particle, classified in classes 514 and 424, subclasses 44 and 93.6, respectively.

VI. Claim 22, drawn to the use of cells according to claim 15 for the preparation of a medicament for the treatment of disorders or diseases of human mammary cells, classified in class 424, subclass 93.2.

VII. Claims 25 and 39, drawn to a pharmaceutical composition comprising the cells according to claim 15, and a method for the treatment of human mammary carcinoma by using said cells, classified in class 424, subclass 93.2.

VIII. Claims 26-36, drawn to the use of the WAP or MMTV regulatory sequences for the expression of linked therapeutic genes in human mammary cells, classified in 536, subclass 24.1.

The inventions are distinct, each from the other because of the following reasons:

Groups I-III are distinct from each other because they are drawn to different compositions having different chemical structures, physical properties, and biological functions: a vector, a recombinant retroviral particle or a human cell containing said vector vs. a packaging cell line vs. encapsulated cells. A packaging cell line is different from a usual cell because the packaging cell further contains construct coding for proteins required for packaging and is specifically used for packaging vector into a viral particle. An encapsulated cell comprises a core containing cells and further contains a porous capsule wall, thus, it is different from the

usual cell and the packaging cell. Therefore, groups I-III require separate search and there is serious burden to search all three groups. Thus, groups I-III are patentably distinct from each other.

Groups IV and VI are distinct from each other because they are drawn to materially different methods having different compositions that differ in chemical structures, physical properties and biological functions: a DNA construct or a recombinant viral particle vs. a cell containing said DNA construct. They are drawn to different methods that differ at least in method steps, reagents used, dosages and schedules used, response variables, and criteria of success. They have different classifications and require separate searches. Thus, groups IV and VI are not obvious variants and are patentably distinct. Similarly, groups III, V and VII are patentably distinct from each other for the same reason.

Groups III, V and VII, groups IV and VI and group VIII are distinct from each other because they are drawn to different scientific considerations: a method for treatment of human mammary carcinoma, the preparation of a medicament for the treatment of disorders or diseases of human mammary cells, and the use of the WAP or MMTV regulatory sequences for the expression of linked therapeutic genes in human mammary cells. They are materially different methods that differ in objectives, method steps, reagents used, dosages and schedules used, response variables, and criteria of success. They have different classifications and require separate searches. There is serious burden to search all these groups. Thus, groups III, V and VII, groups IV and VI and group VIII are not obvious variants and are patentably distinct.

Invention I and inventions IV-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA construct or vector can be used as a probe and the cells can be used to produce a recombinant protein instead of preparation of a medicament or for treating human mammary carcinoma. Thus, inventions I and inventions IV-VII are patentably distinct from each other.

Invention I and invention VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the WAP or MMTV regulatory sequences can be used as a probe instead of driving gene expression. Thus, inventions I and invention VIII are patentably distinct from each other.

Groups II-III are unrelated to groups IV-VIII because the product of groups II-III is not involved or otherwise used in the process of groups IV-VIII. Thus, groups II-III are patentably distinct from groups IV-VIII.

Upon election of one group from groups I-VIII, further restriction is required. WAP and MMTV regulatory sequences are totally different sequences that have different nucleotide sequences and their biochemical and biological functions are different from each other. A search for WAP regulatory sequence does not require a search for MMTV regulatory sequence and vice versa. They require separate search and there is serious burden to search both WAP and MMTV regulatory sequences. WAP and MMTV regulatory sequences are patentably distinct from each

other. Thus, applicants are required to select either WAP or MMTV regulatory sequence for examination. It should be noted that this is a restriction requirement rather than an election of species.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER